LEISTUNG

LUNG VENTILATOR
PR4D-02

R 04-04 (24) REV 06

CERTIFICATE GMP
NBR ISO 9001:2008
EN ISO 13485:2003 + AC 2009

CONTENTS

PR4D-02

PEDIATRIC - ADULT

GUIDELINES AND DECLARATIONS OF LEISTUNG EQUIPAMENTO LTDA. ABOUT ELECTROMAGNETIC COMPATIBILITY (EMC)

<table>
<tr><th colspan="3">Manufacturer guidelines and declarations – Electromagnetic emission</th></tr>
<tr><td colspan="3">The PR4D-02 is designated for use in electromagnetic ambience as specified bellow. It is recommended that the PR4D-02 user ensures it to be utilized in such ambience.</td></tr>
<tr><th>Emission tests</th><th>Compliance</th><th>Electromagnetic ambience - guidelines</th></tr>
<tr><td>RF Emission
ABNT NBR IEC CISPR11</td><td>Group 1</td><td>The Lung Ventilator PR4D-02 uses RF energy only for its internal functions. However, its RF emissions are very low and are unlikely to cause any interference in nearby electronic equipments.</td></tr>
<tr><td>RF Emission
ABNT NBR IEC CISPR11</td><td>Class A</td><td rowspan="3">The Lung Ventilator PR4D-02 is suitable for use in all non-residential establishments and for those directly connected to public network distribution of low voltage electricity that supplies buildings for domestic use.</td></tr>
<tr><td>Harmonic Emissions IEC 61000-3-2</td><td>Not Applicable</td></tr>
<tr><td>Emissions due to the fluctuation of voltage flicker IEC 61000-3-3</td><td>Not Applicable</td></tr>
<tr><td>RF Emission
CISPR 14-1</td><td>Complies</td><td>The Lung Ventilator PR4D-02 is not suitable for interconnection with other equipment.</td></tr>
<tr><td>RF Emission
CISPR 15</td><td>Complies</td><td>The Lung Ventilator PR4D-02 is not suitable for interconnection with other equipment.</td></tr>
</table>

Manufacturer Guidance and Declarations – Electromagnetic immunity			
The **PR4D-02** is designated for use in electromagnetic ambience as specified bellow. It is recommended that the PR4D-02 user ensures it to be utilized in such ambience.			
Emission Tests	**Test Level** **ABNT NBR IEC 60601**	**Conformity Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharges (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by air	Not applicable	Floors should be wooden-made, concrete or ceramic. If the floors are covered with synthetic material, relative humidity should be at least 30%.
Fast Transient Burst (FTB) IEC 61000-4-4	± 2 kV at Inlet line ± 1kv at I/O lines	Not applicable	Quality of power supply should be the same of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Quality of power supply should be the same of a typical commercial or hospital environment.
Voltage drops, short interruptions and voltage variations on the lines of power input IEC 61000-4-11	< 5% $\mathbf{U}_t$ (> 95% voltage drop of Ut) by 0.5 cycles. 40% Ut (60% voltage drop of Ut) by 5 cycles 70% Ut (30% voltage drop of Ut) by 25 cycles. < 5% Ut (> 95% voltage drops of Ut) by 5 seconds.	Not applicable	Quality of power supply should be the same of a typical commercial or hospital environment.
Magnetic fields at power line frequency	3 A/m	Not applicable	Magnetic fields at power supply frequency should be the same of a typical commercial or hospital environment.

Manufacturer Guidance and Declarations – Electromagnetic Immunity

The **Lung Ventilator PR4D-02** is intended for use in electromagnetic environment specified below. It is recommended that the client or user of **Lung Ventilator PR4D-02** ensure that it is used in such environment.

Emission Tests	Test Level ABNT NBR IEC 60601	Conformity Level	Electromagnetic Environment – Guidance
RF Conducted IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz out of bandwidth [A] ISM	Not applicable	RF portable and mobile communication equipments should not be used near any part of the **Lung Ventilator PR4D-02**, including cables, with separation distance less than the recommended, calculated from the equation applicable to the transmitter frequency. Separation distance recommended: $d = 1{,}16\ [\boldsymbol{P}]^{1/2}$ $d = 1{,}2\ [\boldsymbol{P}]^{1/2}$
RF Radiated IEC 61000-4-3	10 Vrms 150 kHz to 80 MHz out of bandwidth [A] ISM 10 V/m 80 MHz to 2,5 GHz		$d = 1{,}2\ [\boldsymbol{P}]^{1/2}$ 80 MHz to 800 MHz $d = 2{,}3\ [\boldsymbol{P}]^{1/2}$ 800 MHz to 2,5 GHz Where ***P*** is the maximum nominal power output of transmitter, in watts (W), according to transmitter manufacturer, and ***d*** is the recommended separation distance, in meters (m). [B] The field intensity established by RF transmitter, as determined by electromagnetic inspection at the local[C] should be less than compliance level in each frequency band [D]. Interference may occur around the equipment marked with this symbol. 

NOTE 1. At 80 MHz and 800 MHz applies the highest range of frequency.

NOTE 2. This guidance may be not applicable in all situations. The electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

A The bandwidth ISM (Industry, medical and scientific), between 150 kHz and 80 MHz are 6.765 MHz; 13.553 MHz to 13.564 MHz; 26.957 MHz to 27.283 MHz and 40.66MHz to 40.70MHz.

B The compliance level in the bandwidth ISM between 150KHz and 80MHz and in the frequency range between 80MHz to 2,5GHz, intends to reduce the probability of mobile and portable communication equipments to cause interference if they are inadvertently brought to the patient´s environment. For this reason, an additional factor of 10/3 is used to calculate the recommended separation distance for transmitter in range of frequency.

C The field intensity established by fix transmitters, like base transceiver stations, telephone (cellular and wireless), land mobile radio, amateur radio, AM and FM transmitter and TV transmitter, can´t be predicted theoretically with accuracy. To evaluate the electromagnetic environmental due to RF fix transmitters, it is recommended to consider a local electromagnetic inspection. If the local field intensity where the **Lung Ventilator PR4D-02** is located exceeds the above applicable RF compliance level, the **Lung Ventilator PR4D-02** should be observed in order to verify the normal operation. If an unusual performance is observed, additional procedure may be necessary, such as reorienting or replacement of **Lung ventilator PR4D-02**.

D Above the frequency range of 150kHz, the field intensity should be smaller than (v1) V/m.

Recommended separation distances between portable and mobile RF communication equipments and the Lung Ventilator PR4D-02

The **Lung Ventilator PR4D-02** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Lung Ventilator PR4D-02** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Lung Ventilator PR4D-02** recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**			
	150 kHz to 80 MHz out of Bandwidth ISM $d = 1{,}16\ [\boldsymbol{P}]^{½}$	150 kHz to 80 MHz out of Bandwidth ISM $d = 1{,}2\ [\boldsymbol{P}]^{½}$	80 MHz to 800 MHz $d = 1{,}2\ [\boldsymbol{P}]^{½}$	800 MHz to 2,5GHz $d = 2{,}3\ [\boldsymbol{P}]^{½}$
0,01	0,11	0,12	0,12	0,23
0,1	0,36	0,37	0,37	0,72
1	1,16	1,2	1,2	2,3
10	3,68	3,79	3,79	7,27
100	11,67	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

NOTE 2 At bandwidth ISM (Industrial, Scientific and Medical), between 150 kHz and 80 Mhz, there are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957MHz to 27,283 MHz e 40,66 MHz to 40,70 MHz.

NOTE 3 An additional margin of 10/3 is used to calculate the separation distance recommended for transmitters in the bandwidth ISM between 150kHz and 80Mhz and the bandwidth 80 MHz to 2,5 GHz to reduce the interference probability from communication mobile equipment could cause if it be carried unwarned in patient area.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Chapter 1

PRESENTATION

In this User Manual, are presented the necessary information for the correct use of the **Lung Ventilator PR4D-02.** The indications relating to enforcement and regulations, mentioned in this manual, is a guideline, the physician should adapt, as their criterion, the needs of patients.

LEISTUNG EQUIPAMENTOS LTDA.
202 João Ropelatto St.
City: Jaraguá do Sul – Santa Catarina
District: Nereu Ramos
POSTAL CODE: 89265-300
Phone: 55 (47) 3371-2741
Fax: 55 (47) 3371-9267
CNPJ 04.187.384/0001-54
Estate registration 254.417.108
Technical Supervisor: Engº Fernando Alves Negrão CREA/SC 0771605
Legal Supervisor: Marcelo Javier Fernandez _____
Operation authorization ANVISA No. GHL3983MX9H2
Certificate GMP:
Registry ANVISA No. 80203470007
Website: www.leistungbrasil.com/eng
E-mail: leistung@leistungbrasil.com

GENERAL	
MODEL	**PR4D-02**
Registry ANVISA	**No. 80203470007**
MEDICAL DEVICE CLASSIFICATION	**CLASS III**
OPERATION MODE	**Continuous operation**
Classification according to type against electrical shock (insulation).	**CLASS II Internally Energized Device** 
Classification according to type of protection against electrical shock (applied part).	**TYPE B** 
Level of protection against water penetration	**IPX0**
 **Equipment not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide**	

PHYSICAL CHARACTERISTICS	PARAMETERS	VALUES
Dimensions (Ventilator)	High	150 mm
	Width	270 mm
	Depth	230 mm

EXTERNAL POWER SOURCE	
NOMINAL VOLTAGE	10.5 V to 14V ⎓
NOMINAL CURRENT	1.20A ~ 0.85A ⎓
NOMINAL POWER	12.5 W
INPUT FUSE	2.5A/250V - 20mm SB
⚠ REPLACE THE FUSE ONLY WITH OTHER WITH THE SAME CURRENT AND VOLTAGE SPECIFICATIONS	

INTERNAL POWER SOURCE		
Nominal voltage	12 V ⎓	
Nominal capacity	2.2Ah	
Type	VRLA (Sealed, does not emit gas)	
Autonomy	Complete battery charge 77ºF (25ºC)	120 minutes autonomy
Capacity affected by temperature	104ºF (40ºC) 77ºF (25ºC) 32ºF (0ºC) 5ºF (-15ºC)	102% 100% 85% 65%
Auto-discharge 68ºF (20ºC)	Capacity after 3 months Capacity after 6 months Capacity after 12 months	90% 80% 60%
Maximum Discharge Current 77ºF (25ºC)	48A (5s)	
Charge (Floating Voltage)	Floating 77ºF (25ºC)	13.6 – 13.8V / 1.25A (max).
Charging Time (Battery Discharged)	Vmin=10.5V	4 Hours
Maximum temperature	131ºF (55ºC)	
Internal fuses	2.5A 20mm SB	
SPECIFICATIONS INFORMED BY BATTERY MANUFACTURER.		
⚠ THE INTERNAL BATTERY AND FUSE ARE NOT REPLACEABLE BY OPERATOR		
⚠ THE SWITCHING FOR INTERNALLY BATTERY OCCURS AUTOMATICALLY WITHOUT THE NECESSITY OF EXTERNAL INTERVENTION. IT DOES NOT MODIFIES THE EQUIPMENT OPERATION OR INSPIRATORY PRESSURE AT THE OUTPUT FOR THE PATIENT.		

ENVIRONMENTAL SPECIFICATIONS		VALUES
Environment Temperature	Operation	10ºC to 35ºC
	Storage – Transport	2ºC to 40ºC (*)
Relative Humidity	Operation	10% to 95% Not condensable
	Storage – Transport	0% to 95% Not condensable
Atmospheric Pressure	Operation	66 – 100 kPa
	Storage – Transport	66 – 100 kPa
PNEUMATIC INPUTS		
OXYGEN	Input DISS 9/16” – 18	

PRESSURE	From 2.8 to 7 kg/cm^2
FLOW	Up to 100 l/min

	USE ONLY MEDICAL GRADE GAS.
	THE MEASURE OF VOLUME AND PRESSURE IS STANDARDIZED BY BAROMETRIC PRESSURE AT SEA LEVEL, BODY TEMPERATURE AND WATER VAPOR SATURATE (BTPS) AND THEY ARE ADJUSTED IN FUNCTION OF ALTITUDE.
	(*) THE STORAGE OF THE LUNG VENTILATOR FOR LONG PERIODS AT TEMPERATURE GREATER THAN 27ºC, OR WITHOUT ELECTRICAL CONNECTION FOR PERIODS GREATER THAN 2 MONTHS, MAY AFFECT THE INTERNALLY BATTERY UTILE LIFE.

WARNINGS, CAUTIONS AND NOTES

WARNINGS

	⇒ Constant attention of specialized personnel is required when patient is connected.
	⇒ Operation problems require immediate corrective action.
	⇒ The professional in charge of its use should, using your own criterion and knowledge, adjust the equipment according to the patient needs.
	⇒ Do not use this equipment in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
	⇒ Do not use anti-static tubes or electrical conductor in the patient circuitry.
	⇒ Do not sterilize the equipment with ethylene oxide. There is a high probability to occur irreversible damage in the ventilator components.
	⇒ The equipment may be affected by High Frequency Electromagnetic Interference (such as cellular, wireless telephone, defibrillators, electro-surgical knifes, magnetic resonance, etc.). Keep these emission sources at least 3(three) meters away from the equipment.
	⇒ Before first utilization and after utilization in each patient, it is necessary to clean the ventilator. To sterilize the accessories, follow the instructions on chapter 8.

PRECAUTIONS

	⇒ During the warranty period, the stay or movement of equipment should be performed with the original packaging, with its internal correspondent protection, otherwise will result in loss of warranty.
	⇒ Never sterilize the ventilator, the internal components is not compatible with sterilization techniques.
	⇒ Follow the instructions at chapter 8 for equipment cleaning and accessories sterilization.
	⇒ Never operate the equipment exposing it to direct heat or sunlight.

	⇒ Never cover or place the equipment in order to block the air entry for cooling.
	⇒ To ensure electrical protections and avoid risk of fire, never change the fuses. If the equipment does not work, contact the Authorized Technical Support.
	⇒ The improper replacement of the fuses nullifies warranty and represents a risk for the equipment operation, operator and patient safety.

NOTES

	⇒ The ventilator is a medical device that has to be operated by qualified and trained personnel, supervised by a doctor.
	⇒ When PR4D-02 is in use, alternative ventilation way must always be available.
	⇒ The PR4D-02 is produced with recyclable materials and should not be thrown into common landfills because it contains toxic materials to nature, for this, contact an authorized dealer.
	⇒ Electric Diagrams, Circuitry Diagrams, component list, repair instructions and training can be provided by Leistung Equipamentos Ltda, by agreement between both parts.
	⇒ Leistung Equipamentos Ltda. is a company of continuous improvement in its products and technical specifications can change without notice.

Chapter 2

INTRODUCTION

The Lung Ventilator PR4D-02 is micro-controlled and developed within the cut edge technology, and offers a reliable working tool for patient transports that need mechanical ventilations.

The **PR4D-02** is easy to operate, because it has an extremely functional designed panel, which permits the operator to use all parameters using few control keys, doing the professional work pleasurable and permits the operator to focus on the patient relationship.

It has an agile and safe patient circuitry interconnection system, preventing any error possibility.

INDICATORS
AIRWAY PRESSURE MANOMETER - LUMINOUS
INSPIRATÓRY TIME – SELECTABLE - LUMINOUS
EXPIRATÓRY TIME – SELECTABLE - LUMINOUS
TOTAL FREQUENCY – SELECTABLE - LUMINOUS
I:E RATIO - SELECTABLE - LUMINOUS
OS THE SELECTABLE INDICATORS ARE VISUALIZED IN TWO SERIES OF LUMINOUS DISPLAYS.

ELECTRÔNIC CONTROLS	
FREQUENCY	5 to 60 cpm
I:E RATIO	1:1.0 to 1:5.0
INSPIRATORY TIME	
EXPIRATORY TIME	
OS THE TIME VALUES DEPEND ON THE SELECTED FREQUENCY AND I:E RATIO.	

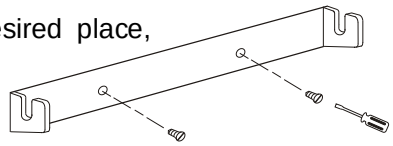
PNEUMATIC CONTROLS
PATIENT FLOW
INSPIRATORY PEAK PRESSURE
ASPIRATOR ADJUSTMENT
FLOWMETER ADJUSTMENT

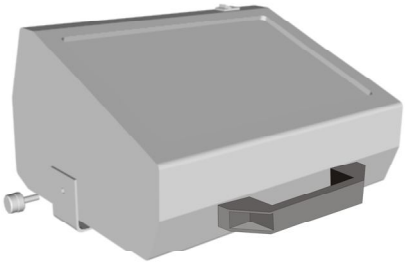
Chapter 3

FIXING AND CONNECTIONS

FIXING

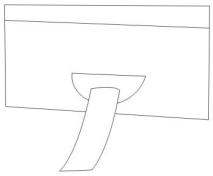
To fix the equipment support with two screws in the desired place, making sure that it is really firm.



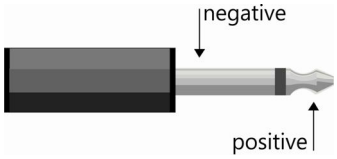


Use the two screws that come laterally in the equipment to fix the equipment at the support.

CONNECTING TO EXTERNAL POWER SOURCE

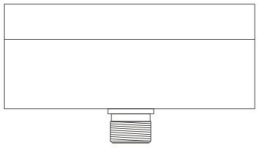


The electrical connection is in the bottom of the equipment and it has a **P10 Plug** with the polarity indicated as shown in the figure.



	VERIFY IF THE CONNECTION OF THE EQUIPMENT IS PROPERLY PERFORMED TO ENSURE A SMOOTH OPERATION.
	VERIFY IF THE JACK (P10 FEMALE) IS COINCIDENT WITH THE PLUG (P10 MALE) BEFORE CONNECT THE EQUIPMENT.

CONNECTING TO GAS SUPPLY



The pneumatic connection is in the bottom of the equipment.

OXYGEN INLET	Male connector DISS 9/16”-18
OXYGEN CONSUMPTION	3 to 6 l/min.
	AT THE EDGE OF THE PRESSURE TUBE ARE USED CORRESPONDENT FEMALE CONNECTORS.
	IT IS POSSIBLE TO USE AS INPUT GAS AIR OR OXYGEN, BUT THE EQUIPMENT DOES NOT MIX THEM.
	THE THREAD CONNECTORS USED IN THE GAS INLET COMPLIES WITH NBR 11906 AND ISO 5359 STANDARD THAT GIVE THE MINIMUM CONDITIONS FOR THIS KIND OF CONNECTORS.
	THE EQUIPMENT GAS INPUT IS MADE WITH A **RETENTION UNIDIRECTIONAL VALVE**, WHICH AVOIDS THE REVERSE FLOW THROUGH INLET PORT REVERSO DE GÁS ATRAVÉS DA PORTA DE ENTRADA

INPUT PRESSURE	
OXYGEN	2.8 to 7 kg/cm^2
MINIMUM FLOW NEEDED	60 l/min.
MAXIMUM FLOW	100 l/min

DO NOT USE THE EQUIPMENT CLOSE TO FLAMMABLE ANESTHETIC GAS, RISK OF FIRE OR EXPLOSION.

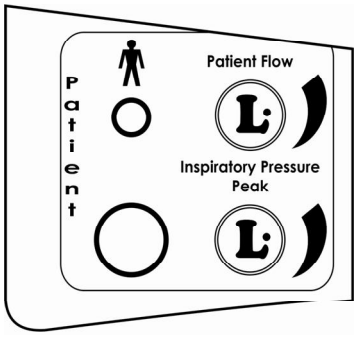
IT MUST BE USED COMPRESSED CLEAN AND DRY OXYGEN, IN ORDER TO AVOID CONTAMINATION THAT CAN AFFECT THE EQUIPMENT AND PRODUCE BAD PERFORMANCE.

THE LUNG VENTILATOR PR4D-02 HAS AN INTERNAL PRESSURE REGULATOR THAT AVOIDS, FOR THE SPECIFIED PRESSURE RANGE, THE INSPIRATORY PRESSURE LOSSES.

DO NOT LET THE INLET GAS PRESSURE BE LESS THAN THE LOW SPECIFIED, THIS MAY CAUSE INSPIRATORY PRESSURE REDUCTION AT PATIENT PORT.

THE LUNG VENTILATOR PR4D-02 DOES NOT HAVE INTERNAL AIR COMPRESSOR, SO WHEN THE INLET GAS ENDS, THE EQUIPMENT STOPS CYCLING.

BREATHING CIRCUIT



The breathing circuit connection is located at the front of the equipment.

Use breathing circuits according to the patient type: adult, pediatric or neonatal, the difference is on the tube internal diameter.

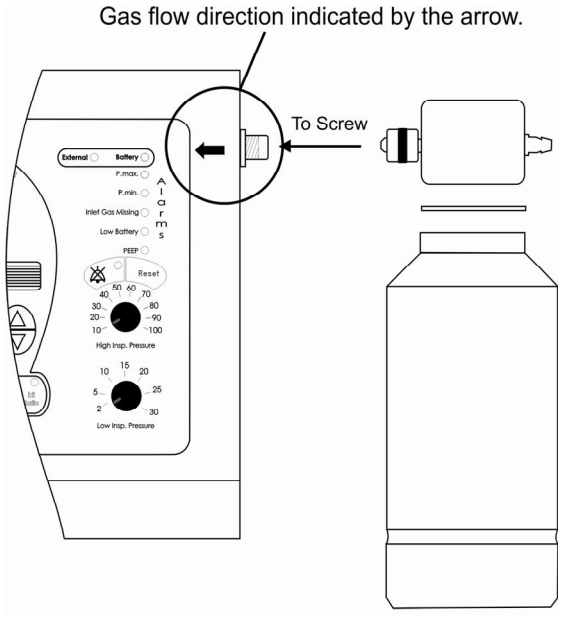
WHEN USING BREATHING CIRCUITS THAT USES WATER TRAPS IN THEIR LINES (INSPIRATORY / EXPIRATORY), ALWAYS VERIFY ITS HERMETICITY, IN ORDER TO AVOID LEAKAGE IN THE BREATHING CIRCUIT.

VERIFY THE PROPER POSITION OF EXPIRATORY VALVE DIAPHRAGM, SEE CHAPTER 6.

THE PATIENT BREATHING CIRCUIT CONNECTOR IS 22MM CONICAL TYPE AND COMPLIES WITH THE STANDARD ISO 5356-1, WHICH STATES THE MINIMAL CONDITIONS REQUIRED FOR THIS KIND OF CONNECTOR.

Aspirator

The aspiration bottle connection is located at the right side of the equipment.

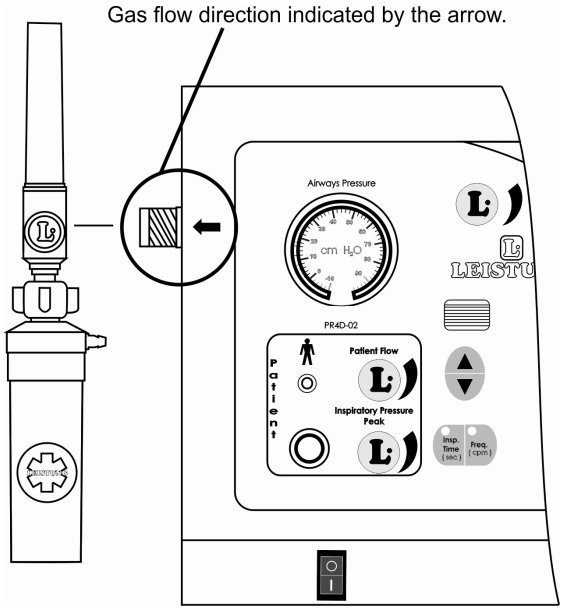


THE THREADED CONNECTION USED IN THE ASPIRATOR (VACCUM CONNECTOR) IS ACCORDING TO THE **NBR 11906 AND ISO 5359** STANDARDS**,** WHICH STATES THE MINIMUM CONDITIONS FOR THIS TYPE OF CONNECTION.

ASPIRATOR SUCTION	
MAXIMUM ASPIRATION	20 cmHg

Flowmeter (Humidifier)

The flowmeter connection is located at the left side of the equipment.



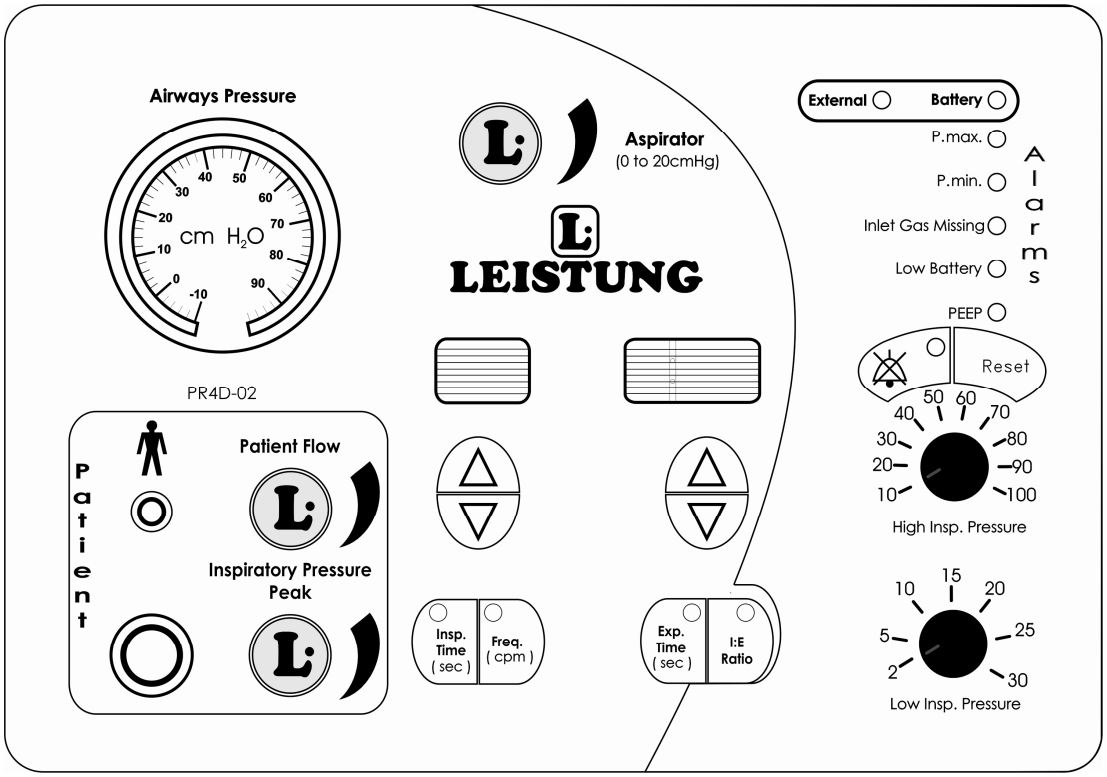
	A THE THREADED CONNECTION USED IN THE O_2 IS ACCORDING TO THE **NBR 11906 AND ISO 5359** STANDARDS**,** WHICH STATES THE MINIMUM CONDITIONS FOR THIS TYPE OF CONNECTION.
	THE HUMIDIFIER IS BUILT ACCORDING TO **ISO 8185** STANDARD, WHICH STATES THE MINIMUM CONDITIONS FOR THIS TYPE OF EQUIPMENT.

Outlet Flow	
OUTLET MAXIMUM FLOW	15 L/min

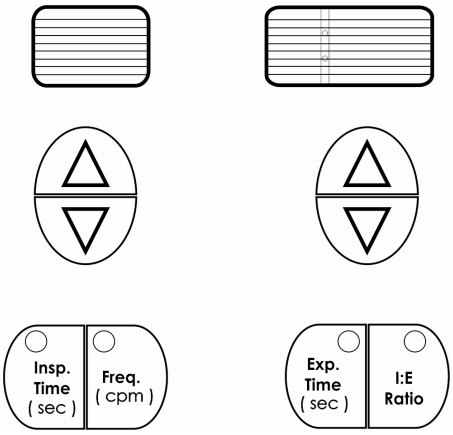
Chapter
4

CONTROLS AND INDICATORS

FRONT PANEL



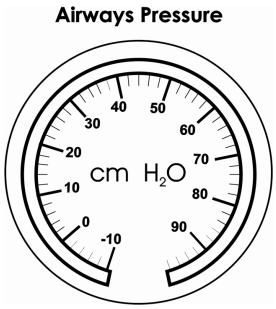
INDICATORS



PR4D-02 has a system of numeric and luminous indicators.

It counts with a set of numeric displays which shows the selected values of inspiratory time, expiratory time (in seconds), I:E ratio and frequency (in cpm)

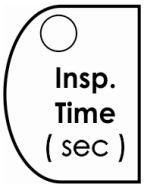
PR4D-02 has also an electronic manometer which shows the airways pressure value in cmH_2O, expressed for Ambient Pressure and Dry Pressure (ATDP)



Electric energy source indicator DC – whenever “External” indicator is alight, the battery is charging.

CONTROLS

INSPIRATORY TIME



With this control the inspiratory time is selected. Pressing this key, a sound is enabled, a luminous indicator is turned on and its numeric value is shown on the left displays set. The inspiratory time is expressed in seconds (s).

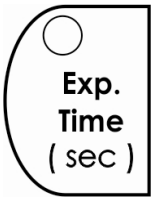
FREQÜÊNCY

With this control the operation frequency is selected. Pressing this key, a sound is enabled, a luminous indicator is turned on and its numeric value is shown on the left displays set. Frequency is expressed in breathes (or cycles) per minute (bpm).

LEFT SELECTION KEYS

With these keys the value of the selected function is modified. Functions which may vary with these keys are inspiratory time and frequency. A sound is enable by pressing any of these keys.

EXPIRATORY TIME

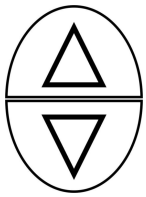


With this control the expiratory time is selected. Pressing this key, a sound is enabled, a luminous indicator is turned on and its numeric value is shown on the right display set. The iexpiratory time is expressed in seconds (s).

I:E RATIO

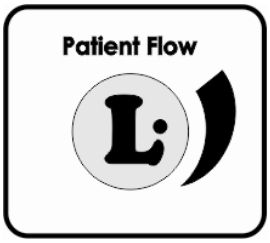
With this control the relation between the inspiratory and expiratory times is selected. Pressing this key, a sound is enabled, a luminous indicator is turned on and its numeric value is shown on the right displays set.

RIGHT SELECTION KEYS

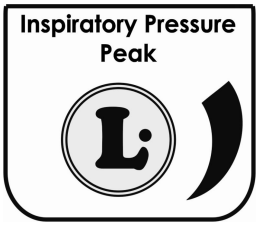


With these keys the value of the selected function is modified. Functions which may vary with these keys are expiratory time and I:E ratio. A sound is enabled by pressing any of these keys.

PATIENT FLOW



With this command the flow of oxygen which will be delivered to the patient by the ventilator is adjusted.

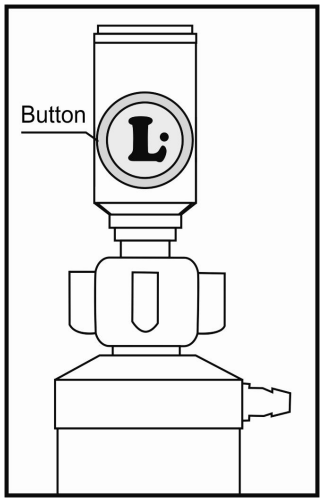


INSPIRATORY PRESSURE PEAK

With this command the maximum of pressure the ventilator will deliver to patient is adjusted. This value is visualized at the electronic manometer of the equipment.

ASPIRATOR

With this command the aspirator suction is adjusted.



HUMIDIFIER

Through flowmeter connected to the cup, this set is used as humidifier. Flowmeter button is used to adjust the flow value in l/min.

Chapter
5

FUNCTIONAL CHARACTERISTICS

ENERGY SOURCES

For its operation this equipment requires electric energy of 12V direct current type (10.5Vdc to 14Vdc). The equipment has in its bottom part outlets for correspondent electric external source and internal support for 12V/2.2Ah battery.

When the inlet voltage is lower than 13Vdc the net sensor may indicates the equipment is operating by battery, to avoid operation with bad low voltage sources.

	Avoid working with external power source lower than 12 Vdc because the battery may be discharged.
	When the external power source or battery reaches values lower than 11Vdc, displays may get turned off and “low battery” alarm will be activated.
	Because it is a transportable equipment, when disconnection of inlet power source occurs, the indicator LED light changes from “external source” to “battery” without activating any sound alarm.

CYCLING

This equipment counts with a micro processor, which commands its operation within a huge frequency range. It makes possible to handle inspiratory curve, adapting it to each clinic case.

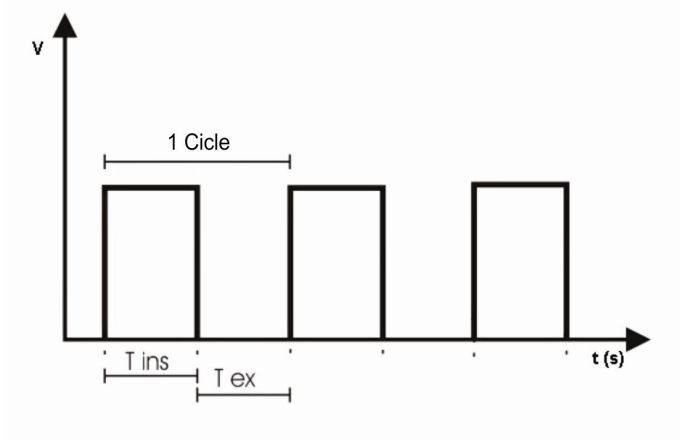
PARAMETERS SELECTION

I/E - Inspiratory time – Expiratory time - Frequency

Parameters	
FREQUENCY	5 to 60 c.p.m
I:E RATIO	1:1.0 to 1:5.0
INSPIRATORY TIME	0.1 to 6.0 seconds
EXPIRATORY TIME	0.5 to 9.9 seconds

Initial Parameters	
FREQUENCY	15 c.p.m
I:E RATIO	1:2.0
INSPIRATORY TIME	1.3 seconds
EXPIRATORY TIME	2.6 seconds

The following graphic illustrates, through electrovalve behavior, the operation of the parameters digitally adjustable. When the electrovalve is turned on, indicated by the high voltage level, there is the inspiratory time and when it is turned off there is the expiratory time.

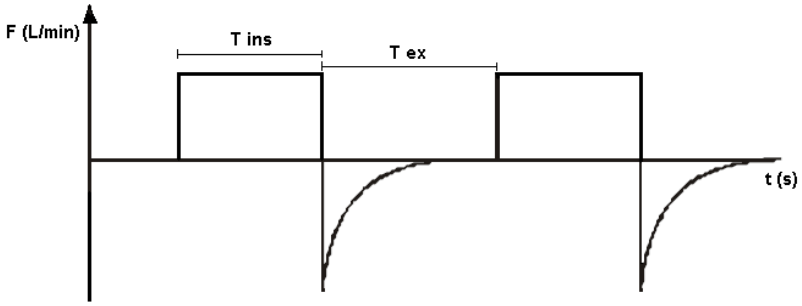


Inspiratory time

Is the time the ventilator provides a gas flow to the patient, generating a positive inspiratory pressure. Changing this parameter changes I:E ratio and frequency.

Expiratory time

Is the time the ventilator stops providing gas to the patient and allows the patient to expire. Changing this parameter changes I:E ratio and frequency.



Respiratory cycle

It is the sum of inspiratory time and expiratory time

$T_{cycle} = T_{ins} + T_{ex}$

Frequency

Indicates the quantity of cycles occurred during one minute. Changing frequency value changes inspiratory time value and expiratory time value, but always maintains the same I:E ratio.

$$F = \frac{60}{T\ ciclo}$$

I:E Ratio

It is a proportion between inspiratory time and expiratory time. Changing I:E ratio changes inspiratory time and expiratory time.

$$I:E = \frac{Tins}{Tex}$$

Exemple:

For initial parameters:

$T_{cycle} = T_{ins} + T_{ex}$

$T_{cycle} = 1.3 + 2.6 =$ **3.9 s**

$$F = \frac{60}{3,9}$$

F = 15 c.p.m.

$$I:E = \frac{Tins}{Tex} = \frac{1,3}{2,6} = \frac{1}{2}$$

If inspiratory and expiratory times are changed to 3.0 s:

$T_{cycle} = T_{ins} + T_{ex}$

$T_{cycle} = 3.0 + 3.0 = 6.0$ **s**

$$F = \frac{60}{6,0} = 10 \text{ c.p.m.}$$

$$I:E = \frac{Tins}{Tex} = \frac{3,0}{3,0} = \frac{1}{1}$$

PR4D-02 has frequency and I:E ratio as main parameters because inspiratory and expiratory time values depend exclusively on them.

Adjusting parameters:

1 – Choose the frequency. You can use the annex 4 as orientation.

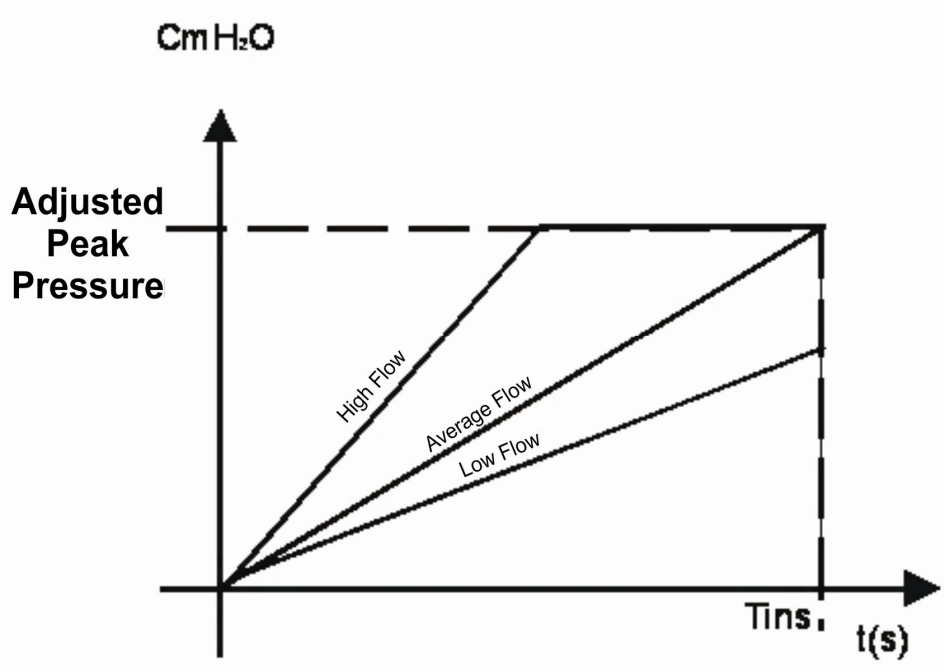
	ANNEX 4 TABLES MAY BE USED AS ORIENTATION TO DETERMINE THE FREQUENCY, ACCORDING TO PATIENT WEIGHT, BUT THE OPERATOR MUST ADJUST THE PARAMETERS ACCORDING TO HIS OWN CRITERIA, IN ORDER TO SUPPORT THE PATIENT.

2 – Adjust I:E ratio, inspiratory and expiratory time values are automatically adjusted.

	THE STEPS ILUSTRATED HERE ARE ONLY ORIENTATIVE, THE PARAMETERS ADJUSTMENT MUST BE DONE BY THE OPERATOR ACCORDING TO HIS OWN CRITERIA.
	CHANGING I:E RATIO, INSPIRATORY AND EXPIRATORY TIMES AND THE FREQUENCY, MAY CHANGE OTHER PARAMETERS BECAUSE THEY ARE ALL CONNECTED.

FLOW AND INSPIRATORY PRESSURE ADJUSTMENT.

For a determined inspiratory maximum adjusted peak pressure valuePara um determinado valor de Pico de Pressão Inspiratório máximo ajustado, patient flow value is what determines the flow ascendant ramp inclination. As PR4D-02 is time controlled and pressure limited, the adjusted maximum pressure will never be overpassed. If inspiratory time value is not enough and flow adjusted value is low, may occur that the equipment will not reach maximum pressure value.



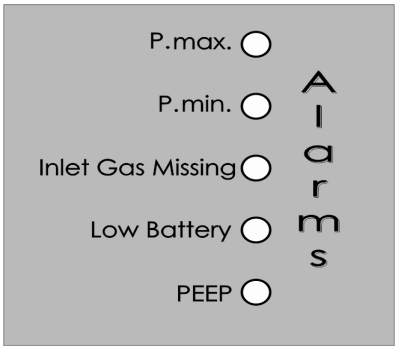
O_2 CONCENTRATION VARIATION

O_2 concentration variation is done through inspiratory flow adjusted value and may vary from 35% (maximum inspiratory flow) to 50% (minimum inspiratory flow) and for values within this range the O_2 concentration assume values between 30% and 50% approximately.

Chapter
6

ALARMS SYSTEM

ALARMS PROGRAMMING



They are located at the right side of the panel a variety of alarms, each one with specific roles which grants safety during ventilation, minimizing the risks and detection time of ventilation anomalies which implies on risks for the patient.

Always an alarm is triggered, besides the sound signal, a LED light signal starts flashing, indicating the cause of the alarm.

Upon solving the cause of the alarm, automatically or by the operator, the sound signal stops and the LED indicator flashing stops, maintaining it turned on continually.

- ALL ALARMS ARE HIGH PRIORITY ONES AND REQUIRE CORRECTIVE IMMEDIATE ACTION BY THE OPERATOR.

AIRWAYS PRESSURE ALARMS

To monitor the respiratory system pressure during inspiration.

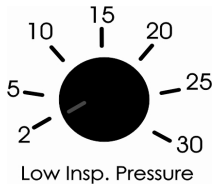
P.max.

Maximum Pressure: interrupts the inspiration if inspiratory pressure reaches a determined pressure level, protecting the lung against pressure intensity that may cause a barotrauma. It is activated at any time during inspiration and remains up to one cycle after problem solution.

The level for alarm activation is adjusted through the “High Ins. Pressure”, located below the indicative LED’s and varies from 10 to 100 cmH_2O.

P.min.

Minimum Pressure: warns if during inspiration the adjusted minimum pressure value is not reached, which may be caused by an accidental disconnection from the equipment or patient circuit leakage. It is activated by inspiratory pressure at the end of inspiration measurement. It is necessary three inspiratory cycles to get activated and one cycle to get deactivated after problem solution.



The value for trigger the alarm is adjusted by the “Low Insp. Pressure”, located below the indicative LED’s and varies from 2 to 30 cmH_2O.

THE MAXIMUM PRESSURE ALARM VALUE LIMITS THE ADJUSTMENT VALUE OF INSPIRATORY PRESSURE.

INLET GAS MISSING ALARM

Inlet Gas Missing ○

Measures the pressure of inlet gas at the equipment gas input, whenever the gas pressure is lower than 3.5 Kgf/cm^2 the alarm is triggered, returning to the normal condition after resolved the problem.

LOW BATTERY ALARM

Battery Low ○

Measures the battery voltage level of the equipment, which for values lower than 11V (equivalent to 90% of battery autonomy) the alarm is triggered, returning to the normal condition after resolved the problem.

PEEP ALARM

Peep ○

Measures the pressure level at the end of expiration; it is triggered when this pressure varies in + or – 3 cmH_2O of the predetermined value. It is necessary two expiratory cycles to trigger this alarm, returning to the normal condition after resolved the problem. The adjustment of this alarm is made by the following way:

- The PEEP value is adjusted (for this, is necessary to use a PEEP valve at the exahlatory valve, purchased separately).
- When PEEP alarm starts, “RESET” key is pressed, the PEEP value will be adjusted to the real pressure value of airways at the moment the key was pressed.
- The PEEP value will be adjusted only if PEEP alarm was activated.

- THIS ALARM MAY BE USED FOR DETECTION OF CONTINUOUS PRESSURE LIMIT, WHENEVER THE EQUIPMENT STARTS; THE PEEP VALUE IS TAKEN AS BEING 0 CMH_2O AND ANY CONTINUOUS PRESSURE ABOVE 3 CMH_2O AT AIRWAYS WILL TRIGGER THE PEEP ALARM.

- DUE TO OPERATING LOGIC OF THE PEEP ALARM DEPENDS ON “RESET” KEY, ALWAYS BE CAREFULL UPON ACTIVATING THIS KEY, TO AVOID UNDUE ADJUSTMENTS OF PEEP ALARM.

ALARMS DEFAULT CONFIGURATION			
Parameter	**Initial Value**	**Adjustable?**	**Adjustment range**
Max. Ins. Pressure	Depends on adjust.	Yes	10 - 100 cmH2O
Min. Ins. Pressure	Depends on adjust.	Yes	2 - 30 cmH2O
Inlet gas missing	3,5kgf/cmH2O	No	-
Low battery	11V (Battery)	No	-
PEEP	00 cmH2O	Yes	0 – 100 cmH2O

- ALARMS PARAMETERS ADJUSTMENT MUST BE DONE BY OPERATOR, CONSIDERING EACH CLINIC CASE, BEFORE INITIATING THE VENTILATION.

- IT IS RECOMMENDED TO BE CHECKED BY THE OPERATOR OR USER, THE ALARMS VALUE VERIFICATION LIST, SPECIALY IN EVENTUAL CHANGES OF OPERATORS.

- AFTER TOTAL ENERGY/BATTERY LOSS AND FURTHER RETURN, THE EQUIPMENT RESTARTS WITH THE ALARMS DEFAULT CONFIGURATION.

ALARMS VALUE VERIFICATION LIST		
PATIENT	**OPERATION MODE**	**CHECK**
ADULT	PCV	P max P min
PEDIATRIC	PCV	P max P min

ALARMS SYSTEM INTEGRITY TEST

1 – Turn on the equipment, with the test balloon connected to. Through “High Ins. Pressure” button, adjust for a value lower than peak value, shown at the electronic manometer. It must trigger “Maximum Pressure” alarm and after each cycle, outlet flow must be cut.

2 – Adjust the value of Pmin for a value bigger than peak value, shown at the display and disconnect the test balloon. After three cycles of inspiration, it must trigger “Minimum Pressure” alarm.

3 – Maintain PEEP alarm in zero and adjust the PEEP valve for any value. It must triggers PEEP alarm.

4 – Disconnect the O_2 hose from gas inlet. It must triggers “Inlet Gas” alarm.

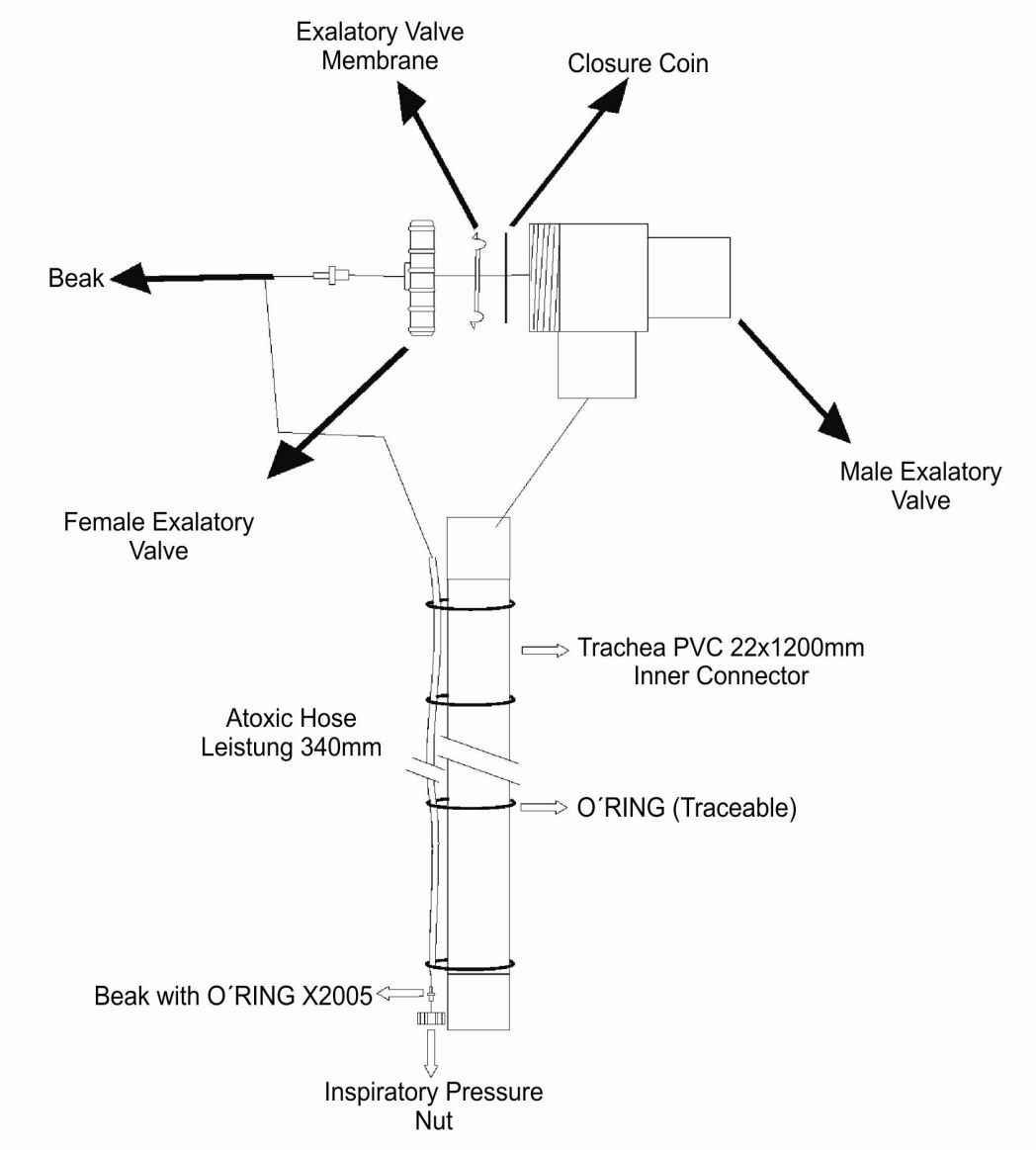
5 – Disconnect the power cable from the external power source. It must turn on “Battery” LED.

6 – Make the inlet power source voltage be lower than 100.0 Vdc. It must trigger “low battery” alarm.

- EACH TEST IS INDEPENDENT OF EACH OTHER, SO THEY CAN BE TEST IN OTHER ORDER THAT WAS SUGGESTED.
- THE TIME BETWEEN PARAMETER ADJUSTMENT AND ALARM ACTIVATION MAY VARY ON EACH TEST.

- IT IS RECOMMENDED THIS TEST TO BE DONE ALONG WITH PREVENTIVE MAINTENANCE.

PATIENT CIRCUIT MOUNTING



⚠	WHEN RESPIRATORY CIRCUIT COMPONENTS OR OTHER COMPONENTS OR SUBSETS, THE PRESSURE GRADIENT, THROUGH VENTILATOR RESPIRATORY SYSTEM, MEASURED FROM CONNECTION PATIENT PORT, MAY INCREASE.
⚠	A BAD CLOSING OF THE DIAPHRAGM MAY WILL RESULT IN A WRONG EXPIRED PARAMETERS LECTURE.
⚠	THE DIAPHRAGM MUST LEAN THE COVER ACOMMODATION. FIRST PUT IT IN THE COVER AND ENSURES THAT IT IS WELL LEANT, ONLY THEN THREAD WITH THE BODY.

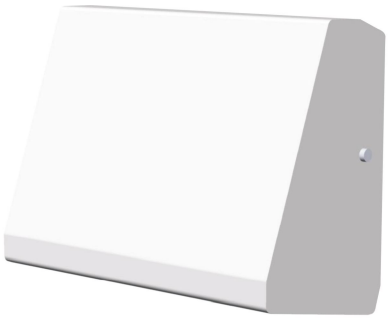
	DO NOT THREAD STRONGLY THE COVER WITH THE BODY WHEN THE SCREW GETS IN THE END. THREAD IT SOFTLY.
	THE PATIENT CIRCUIT TYPE B IS BUILT WITH MATERIAL CERTIFIED BY FDA (FOOD AND DRUGS ADMINISTRATION) WHICH GRANTS THE BIOCOMPATIBILITY OF THIS MATERIAL. THE COPY OF THE CERTIFICATE CAN BE GOTTEN WITH THE MANUFACTURER.

	THE PATIENT CIRCUIT CONNECTOR IS ACCORDING TO NBR 13476 STANDARDS.
	THE TUBE USED IN THE RESPIRATORY SYSTEM OF THE VENTILATOR IS ACCORDING WITH **NBR13274 AND ISO 5367**, RELATED TO RESPIRATORY TUBES FOR USE IN RESPIRATORY SYSTEMS AND VENTILATORS.

Chapter
7

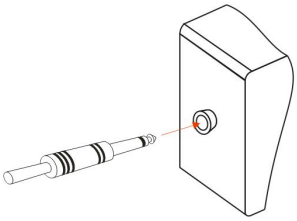
PR4D-02 OPERATION

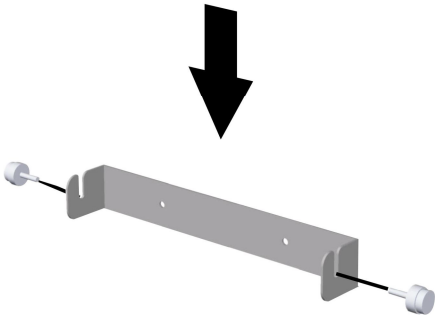
Lung Ventilator PR4D-02 operation.



1 – Fix PR4D-02 on its support.

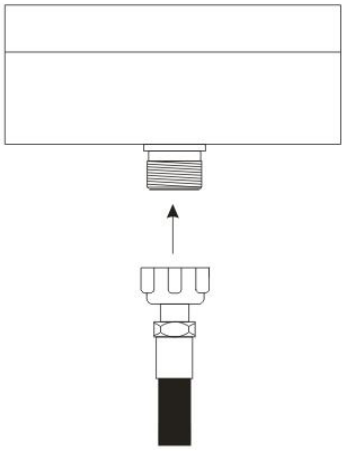
2 – Connect the power source 12Vdc.





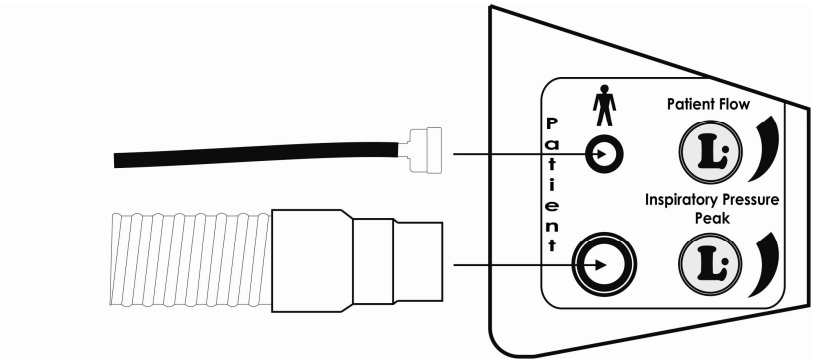
BEFORE CONNECTING, VERIFY IF POWER SOURCING CONDITIONS ARE ACCORDING WITH SPECIFICATIONS OF CHAPTER 1.

3 – Connect pneumatic source (2.8kg/cm^2 to 7kg/cm^2);



BEFORE CONNECTING, VERIFY IF GAS SOURCING CONDITIONS ARE ACCORDING TO THE SPECIFICATIONS OF CHAPTERS 1 AND 3.

4 – Connect the patient circuit to the correspondent connector and the nut of inspiratory pressure (chapter 3), the mounting of the circuit is in chapter 6.



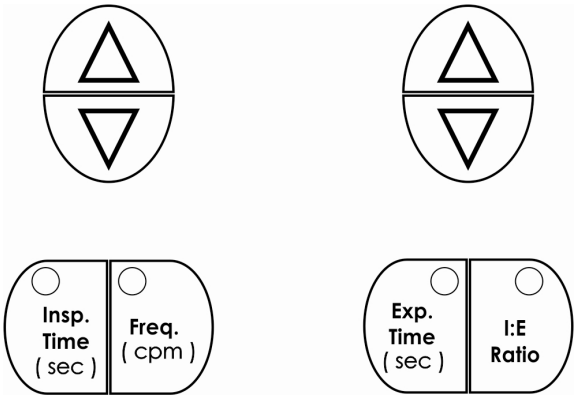
5 – Turn on the “on/off” switch of the equipment.

PR4D-02 HAS THE FOLLOWING INITIAL DEFAULT PARAMETERS VALUES:

Inspiratory Time: 1.3 s

- Expiratory Time: 2.6 s
- Frequency: 15 c.p.m
- I:E ratio: 1:2

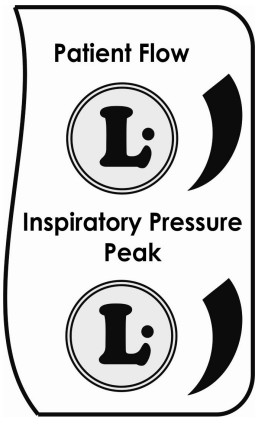
6 – Adjust the parameters of time, frequency and I:E ratio using panel keys (as parameters selection in chapter 5):



DUE TO BE INTRINSICALLY RELATED, CHANGING I:E RATIO, INSPIRATORY AD EXPIRATORY TIMES AND FREQUENCY, MAY CHANGE VALUE OF THE OTHERS.

TABLES OF ANNEX 4 CAN BE USED AS ORIENTATION TO DETERMINE OF THE FREQUENCY, ACCORDING PATIENT WHEIGHT, BUT THE OPERATOR MUST ADAPT THE PARAMETERS AS HIS OWN CRITERIA, TO THE NEEDS OF THE PATIENT.

7 –Adjust maximum pressure through inspiratory pressure peak button and flow delivered to patient through patient flow button (as shown in chapter 4):



THE OPERATOR MUST ADAPT THE PARAMETERS OF PRESSURE AND FLOW AS HIS OWN CRITERIA, TO THE NEEDS OF THE PATIENT.

8 – Connect exhalatory valve of patient circuit to the patient.

THE CONNECTION OF THE LUNG VENTILATOR TO THE PATIENT MUST BE DONE ONLY BY TRAINED PERSONNEL, QUALIFIED FOR THIS FUNCTION.

Aspiration bottle operation

1 – Connect the aspiration bottle to the PR4D-02 connector (Chapter 3);

2 – Connect a hose to the beak of the aspiration bottle.

3 – Open the “Aspirator” button (Chapter 4);

THE ASPIRATION MANEUVER MUST BE DONE ONLY BY TRAINED PERSONNEL, QUALIFIED FOR THIS FUNCTION.

USE ONE OF THE METHODS DESCRIBED AT CHAPTER 8 FOR CLEANING AND STERILIZATION OF THE ASPIRATION BOTTLE.

Humidifier operation

1 – Connect the flowmeter with the humidifier cup containing distilled water or saline solution;

2 – Connect a proper mask at the output of the humidifier;

3 – Open the flowmeter button to get the desired flow value;

Chapter
8

CLEANING, DISINFECTION AND STERILIZATION

The parts in touch with the patient can be completely sterilized.

The protocols which define the method and frequency must be adapted to the procedures of decontamination and cleaning here indicated as guides.

The respiratory circuit and its parts must be replaced sterilized or disinfected elements.

Once removed from the equipment, the patient circuit must be dismounted, so that all its parts get previously cleaned (remove traces of blood and other wastes). The methods enabled for disinfection which depend on thermolability are:

PVC patient circuit, exhalatory valve, aspiration bottle and humidifier cup:

- Ethylene oxide – 55%
- Pasteurization – 75%

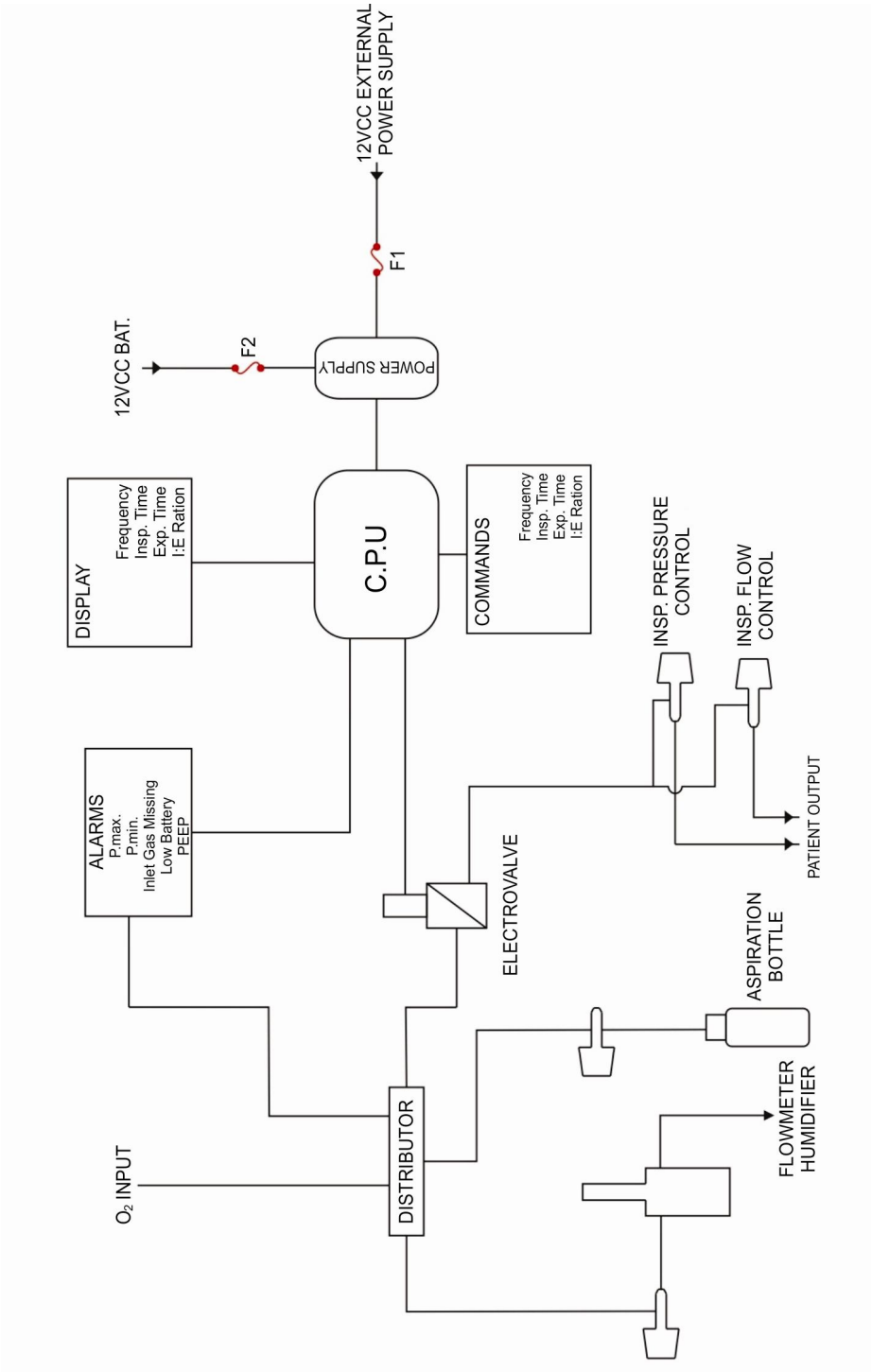
	ETHYLENE OXIDE IS TOXIC, ALL COMPONENTS MUST BE PREVIOUSLY DRIED WHEN PUTTING FOR STERILIZATION, THEY MUST BE VENTILATED TO RELEASE THE RESIDUAL GAS. FOLLOW MANUFACTURER RECOMMENDATIONS.
	THE EXHALATORY VALVE, THE PATIENT CIRCUIT, THE ASPIRATION BOTTLE AND THE HUMIDIFIER CUP ARE NOT AUTOCLAVABLE.
	FOR THE PATIENT CIRCUIT, CONSULT MANUFACTURER RECOMMENDATIONS.
	AVOID USE OF PURE ALCOHOL, CLEANING SOLUTIONS THAT CONTAIN ALCOHOL, SOLVENTS, ACETONE, CHLOROFORM TO CLEAN THE RESPIRATORY TUBES OF PLASTIC PARTS.

	ETHYLENE OXIDE USE MAY ACCELERATE WRINKLES OR ITS DERIVATIVES AND CHANGE PLASTIC CHARACTERISTICS.
	THE RESPIRATOR (ITS CASE) MUST BE NEITHER CLEANED WITH ETHYLENE OXIDE NOR IN AUTOCLAVE.
	PATIENT CIRCUIT MUST BE STERILIZED WITH LOW TEMPERATURE SYSTEMS.

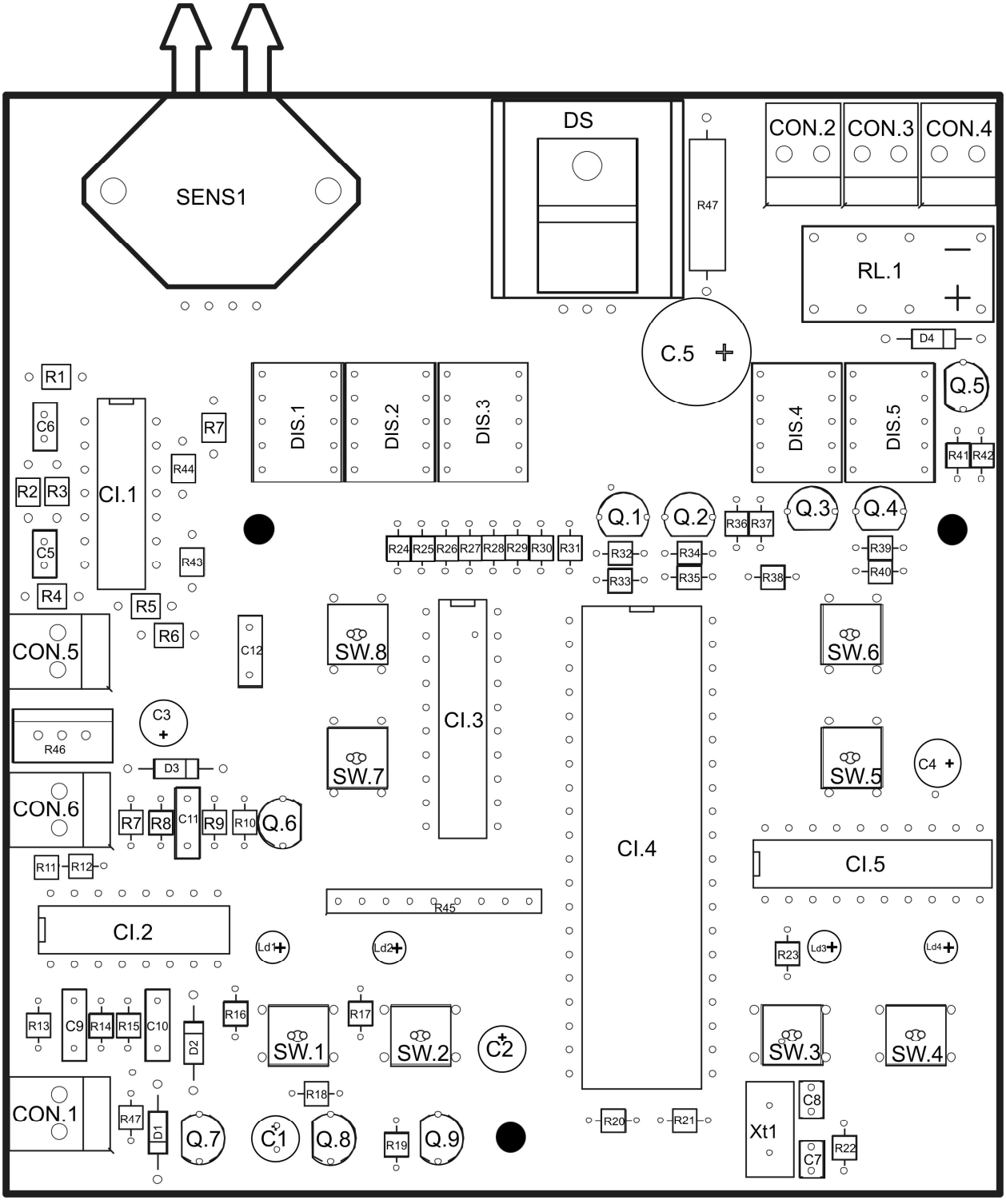
Chapter
9

DIAGRAMS

The figure below represents the pneumatic diagram of PR4D-02 ventilator



The figure below is the marked diagram PR4D-02 CPU board



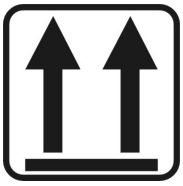
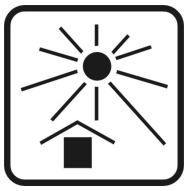
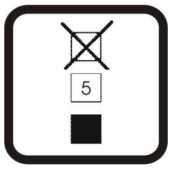
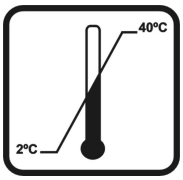
Annex
1

SIMBOLOGY

1 - STANDARD SYMBOLS MEANING PRINTED ON EQUIPMENT, INTERNAL AND EXTERNAL

Symbol	Standard	Description
	IEC 60601-1:1994 Symbol No.417-5032	Alternated Current
	IEC 60601-1:1994 Symbol No.417-5031	Continuous Current
	IEC 60601-1:1994 Symbol No.417-5017	Functional Ground Terminal
	IEC 60601-1:1994 Symbol No.417-5019	Protection Ground Terminal
	IEC 60601-1:1994 Symbol No.348	Warning! Consult accompanying documents.
	IEC 60601-1:1994 Symbol No.417-5007	ON (Connected to a internal / external power source)
	IEC 60601-1:1994 Symbol No.417-5008	OFF (Disconnected from internal / external power source)
	IEC 60601-1:1994 Symbol No.878-02-02	B Type Equipment
	IEC 60601-1:1994 Símbolo No.417-5172	Class II Equipment
	IEC 60601-1:1994 Symbol No.878-03-01	Electrical Shock Hazard
	IEC 417 Symbol No.5016	Fuse
	ISO 15223:2000 Symbol No.3.3	Consult Accompanying Documents

2 – STANDARD SYMBOLS MEANING PRINTED AT EQUIPMENT PACKAGE:

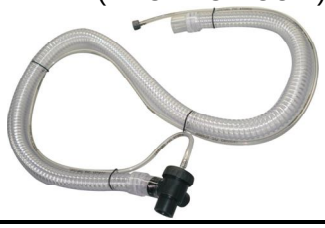
Symbol	Standard	Description
	ISO 780:1997 (E) No. 1	FRAGILE Handle carefully
	ISO 780:1997 (E) No. 3	THIS SIDE UP Indicates de position of the upper side of the package
	ISO 780:1997 (E) No. 4	PROTECT FROM SUNLIGHT The package cannot be exposed to direct sunlight.
	ISO 780:1997 (E) No. 6	PROTECT FROM RAIN The package cannot be exposed to the rain.
	ISO 780:1997 (E) No. 14	MAXIMUM STACKING Indicates the maximum number of packages that can be stacked to storage or transport.
	ISO 780:1997 (E) No. 17	TEMPERATURE LIMIT Indicates the temperature limit for storage and package handling.

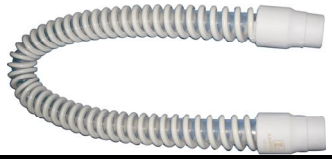
3 – SYMBOLS MEANING PRINTED AT EQUIPMENT USER MANUAL:

Symbol	Standard	Description
	----------	**ADVERTÊNCIA!** **WARNING!** Condition that has the probability to cause damage to the operator or others.
	IEC 60601-1:1994 Symbol No.348	**ATTENTION** Condition that has the probability to cause damage to the equipment, their accessories or others
	----------	**NOTE** Specific points of interest to be considered for a correct use.
	AN 980	**MANUFACTURER**

Annex
2

ACCESSORIES

DESCRIPTION	FUNCTION
PATIENT CIRCUIT WITH EXALATORY VALVE (ADULT CIRCUIT) 	EQUIPMENT-PATIENT INTERFACE **OBS.:** MUST BE USED ONLY THE MODEL THAT ACCOMPANY THE PR4D-02 VENTILATOR
O_2 GAS INLET BEAK 	GAS SUPPLYING
FLOWMETER WITH HUMIDIFIER CUP 	TO MEASURE THE FLOW AND HUMIDIFY O_2.
ASPIRATION BOTTLE 	SECRETION BOTTLE
SUPPORT SHAPE 	TO FIX THE EQUIPMENT IN THE MOBILE UNIT
USER MANUAL	INFORMATION ABOUT OPERATION, REQUIREMENTS AND FUNCTIONS OF EQUIPMENT.

DOBLE CONNECTION (OPTIONAL) 	TO CONNECT TWO O_2 SOURCES, ALLOWING DISCONNECTING ONE OF THEM WITHOUT INTERRUPTING VENTILATOR WORKING. EX. CAN BE USED FOR O_2 CILINDER SWAPING OR FROM AMBULANCE TO GURNEY.
SILICONE TRACHEA (OPTIONAL) 	CAN BE FURNISHED WITH THE EQUIPMENT INSTEAD OF PVC TRACHEA.

Merely illustrative figures

Annex
3

PREVENTIVE MAINTENANCE

	MAINTENANCE MUST BE DONE BY QUALIFIED PERSONNEL AND RESPECTING CORRESPONDING PROTOCOLS.
	THE MANUFACTURER CANNOT BE LIABLE BY INJURY OR DAMAGE CAUSED BY BAD UTILIZATION.

	IT IS RECOMMENDED TO CHANGE THE INTERNAL BATTERY EVERY 4 YEARS.
	ALWAYS CHECK THE INTERNAL BATTERY BEFORE USE, TESTING THE EQUIPMENT WITHOUT EXTERNAL POWER SUPPLY.
	IT IS RECOMMENDED TO CALIBRATE THE VENTILATORY PARAMETERS ANNUALLY, USING CERTIFICATED STANDARDS.

Annex
4

RADFORD TABLE

TABLE USED TO FIND THE FREQUENCY ACCORDING TO PATIENT WEIGHT, IN PEDIATRIC AND ADULT

		FREQUENCY													
kg	**GENDER**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**25**
40	M				X	X	X	X	X	X	X	X	X	X	X
40	F				X	X	X	X	X	X	X	X	X	X	X
45	M				X	X	X	X	X	X	X	X	X	X	X
45	F				X	X	X	X	X	X	X	X	X	X	X
50	M	X	X	X	X	X	X	X	X	X	X	X	X	X	
50	F	X	X	X	X	X	X	X	X	X	X	X	X	X	
55	M	X	X	X	X	X	X	X	X	X	X	X			
55	F	X	X	X	X	X	X	X	X	X	X	X			
60	M	X	X	X	X	X	X	X	X	X	X	X			
60	F	X	X	X	X	X	X	X	X	X	X	X			
65	M	X	X	X	X	X	X	X	X	X	X	X			
65	F	X	X	X	X	X	X	X	X	X	X	X			
70	M	X	X	X	X	X	X	X	X	X	X	X			
70	F	X	X	X	X	X	X	X	X	X	X	X			
75	M	X	X	X	X	X	X	X	X	X	X	X			
75	F	X	X	X	X	X	X	X	X	X	X	X			
80	M	X	X	X	X	X	X	X	X	X	X	X			
80	F	X	X	X	X	X	X	X	X	X	X	X			
85	M	X	X	X	X	X	X	X	X	X	X	X			
85	F	X	X	X	X	X	X	X	X	X	X	X			
90	M	X	X	X	X	X	X	X	X	X	X	X			
90	F	X	X	X	X	X	X	X	X	X	X	X			
100	M	X	X	X	X	X	X	X	X	X	X	X			
100	F	X	X	X	X	X	X	X	X	X	X	X			
110	M	X	X	X	X	X	X	X	X	X	X	X			
110	F	X	X	X	X	X	X	X	X	X	X	X			

TABLE USED TO FIND THE FREQUENCY ACCORDING TO PATIENT WEIGHT, PEDIATRIC AND NEONATAL

		FREQUENCY												
kg	**GENDER**	**16**	**17**	**18**	**19**	**20**	**22**	**25**	**27**	**30**	**35**	**40**	**45**	**50**
8				X	X	X	X	X	X	X	X	X	X	X
8.5				X	X	X	X	X	X	X	X	X	X	X
9		X	X	X	X	X	X	X	X	X	X	X		
9.5		X	X	X	X	X	X	X	X	X	X	X		
10		X	X	X	X	X	X	X	X	X				
11		X	X	X	X	X	X	X	X	X				
12		X	X	X	X	X	X	X	X	X				
13		X	X	X	X	X	X	X	X	X				
14		X	X	X	X	X	X	X	X	X				
15		X	X	X	X	X	X	X	X	X				
20	M	X	X	X	X	X	X	X	X	X				
20	F	X	X	X	X	X	X	X	X	X				
25	N	X	X	X	X	X	X	X	X	X				
25	F	X	X	X	X	X	X	X	X	X				
30	M	X	X	X	X	X	X	X	X	X				
30	F	X	X	X	X	X	X	X	X	X				
35	M	X	X	X	X	X	X	X						
35	F	X	X	X	X	X	X	X						

Annex
5

WARRANTY

Equipment brand LEISTUNG Model PR4D-02

Serial Number ..... **ANVISA No. 80203470007**

Purchased by:.....

Date of Purchase:.....

Chit No......

This equipment has 12 months warranty starting from the purchase date, after that the Manufacturer is responsible for all manufacturing defects.

This warranty is valid only if stamped and rubricated by Leistung Equipamentos Ltda, and the commercial invoice should accompany the equipment.

The conditions for use, installation and maintenance necessary to this equipment should be respected as described in this user manual.

This warranty is denied when:

a) The identification tags is changed or removed;

b) The installation wasn´t executed following user manual indications;

c) If identified electrical installation deficit, flickers, bursts or voltage out of the range specified for this equipment;

d) Damage caused by hits or accidents of any nature;

e) If equipment is handled by non authorized / capacitated personnel.

The installation is responsibility of the buyer.

The LEISTUNG EQUIPAMENTOS LTDA. does not assume any responsibility to bad use or bad installation of the equipment.